

K110105

APR 28 2011



BD

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live healthy lives

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Date of Summary Preparation: January 10, 2011

1. **Submitted By:**

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2. **Device Name:**

Trade Name: BD 23G X 7mm Pen Needle

Common Names: Insulin Pen Needle

Classification Name: Needle, Hypodermic, Single Lumen

Classification: Class II, 21 CFR 880.5570 FMI

3. **Predicate Device:**

BD Pen Needle- K100005 and K051899

Manufactured by: Becton, Dickinson and Company

4. **Device Description:**

BD pen needles are single use, sterile, medical devices designed to be used in conjunction with pen injectors and pen cartridges. Pen needles are used by consumers, caregivers and health care professionals. They are offered in various gauge sizes (29G, 30G, 31G and 32G) and lengths (4mm, 5mm, 8mm and 12.7mm). BD Pen Needles are sterile (gamma irradiation sterilization), non-toxic and non-pyrogenic.

The pen needle assembly consists of a doubled-ended cannula that is assembled into an injection-molded hub using adhesive. The hub has internal threads, which allows it to be screwed onto the pen-injector device. This allows the Non Patient (NP) end of the cannula to penetrate through the rubber septum of the cartridge. The Patient end and NP end of the cannula are lubricated using a silicone based lube for ease of injection and rubber septum penetration. This needle assembly is inserted into a protective injection-molded outer cover and sealed with a peel-away (tear drop) label to provide sterility barrier and tamper evidence. The Outer cover is also used to remove the hub and cannula from the pen. The peel-away label is pre-printed with information, which includes the lot number and needle gauge / length. The individual needle assemblies are packaged in bags and / or cartons, and placed into shippers with appropriate labeling. The shipper cases are palletized and sterilized.

The purpose of the 510(k) is to expand the needle range to include the 23G x 7 mm pen needle size. Future needle range expansions may include 24G to 28G in various lengths for which appropriate verification and validation activities will be conducted. The intended use for the modified device remains the same as the predicate device.

5. **Statement of Intended Use/Indications for Use:**

BD Pen Needle is intended for use with pen injector device for subcutaneous injection of drugs, including insulin and exenatide.

6. **Technological Characteristics:**

The principal device of this premarket notification is the result of a design change to the predicate devices conducted in accordance with Quality System Regulations. The BD 23G X 7mm Pen Needle, modified, is equivalent to the predicate devices, given that:

- Has the same intended use and indications for use as the predicate devices
- Uses the same operating principles
- Incorporates the same basic design

- Is manufactured from the same materials
- Is sterilized using the same mode
- Is sterilized with SAL of 10^{-6}
- Is packaged using similar unit and case materials

The only differences between the BD 23G X 7mm Pen Needle, modified, and the predicate devices are the gauge size, needle length and a larger hub which has the same basic design.

7. **Performance:**

Bench tests relating to the performance of the BD 23G X 7mm Pen Needle were conducted.

The principal device demonstrated equivalent performance to the predicate devices during bench testing. Bench testing consisted of:

Tubing diameters	Per ISO 11608-2, section 4.3.1 (tubing dimensions meet OD and ID requirement).
Patency of lumen	Per ISO 11608-2, section 4.4 (stylet, having a diameter equivalent to $80\% \pm 2\%$ of lumen ID passes through freely).
Needle points	Per ISO 11608-2, section 4.5 (visually sharp at 2.5X magnification, designed to minimize coring and fragmentation).
Non-Type A Needle (length)	Per ISO 11608-2, section 4.3.3 (patient end within indicated length ± 1.25 mm)
Cannula load test (No pre-conditioning)	Per ISO 11608-2, section 4.9 and 9. ISO 7864 Section 13.1 (cannula holds force of 34N for 5 seconds).
Cannula load test (with pre-conditioning)	Per ISO 11608-2, section 4.9 and 9. ISO 7864 (cannula holds force of 34N for 5 seconds).
Lubrication	Per ISO 11608-2, section 4.7 (no visible droplets inside/outside surfaces of cannula).
Compatibility Testing	Per ISO 11608-2, section 4.10 (connectivity (torque)).
Cover Impact Testing	BD design verification protocol Meets acceptance criteria

The results of these tests demonstrate that the BD 23G X 7mm Pen Needle, modified, perform equivalent to the predicate devices and is safe and effective when used as intended.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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APR 28 2011

Re: K110105
Trade/Device Name: BD 23G X 7mm Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: April 21, 2011
Received: April 22, 2011

Dear Mr. Amato:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

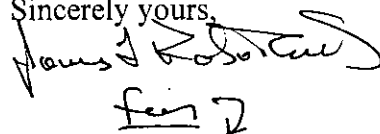
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: BD 23G X 7mm Pen Needle

Indications For Use:

BD Pen Needle is intended for use with pen injector device for subcutaneous injection of drugs, including insulin and exenatide.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

RL C. Oly 4/28/11
(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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